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Attachment 25
510(k) Summary Statement for the
Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems

OCT 11 2002

I. General Information

Submitter:	Lumenis, Inc. 2400 Condensa Street Santa Clara, CA 95051
Contact Person:	Anne C Worden Acting VP, Regulatory & QA
Summary Preparation Date:	March 11, 2002

II. Names

Device Names:	Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems
Primary Classification Name:	Laser Powered Surgical Instrument (and Accessories)

III. Predicate Devices

- ESC Medical Systems EpiLight (K991935, K994014);
- ESC Medical Systems MultiLight (K994014);
- ESC Medical Systems Photoderm HR (K991935);
- ESC Photoderm Nd:YAG Accessory (K980537);
- ESC Photoderm PL (K960772);
- ESC Photoderm VL (K950493);
- Candela SPTL-1e Pulsed Dye laser system (K011092);
- Candela Dynamic Cooling Devices (K001589, K951033);
- MedArt 520 Cooling System (K000503);
- OptoMed DermaCool Skin Cooling Device (K990417); and
- Coherent Epidermal Chiller Tip (K960032).

IV. Product Description

Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems are comprised of the following main components:

- A light/laser system console (including software and control electronics);
- A control and display panel;
- One or two attached handpiece(s);
- A skin cooling device integrated into the handpiece (on some handpieces);
- A trigger button integrated into the handpiece;
- A remote interlock connector (disables light/laser when treatment room door is opened).

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V. Indications for Use

The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems (and the delivery accessories that are used with them to deliver light and/or laser energy) are indicated for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology. The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems is indicated for the treatment of tattoos and benign pigmented epidermal and cutaneous lesions, including warts, scars and striae, and the treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations, and the removal of unwanted hair from all skin types, and to effect stable long-term, or permanent[8], hair reduction in skin types I-V through selective targeting of melanin in hair follicles (515 – 1200 nm), and for the coagulation and hemostasis of vascular lesions and soft tissue (1064 nm).

In addition, the Lumenis Family of IPL/Nd:YAG laser systems (1064 nm) is safe and effective when indicated for coagulation and hemostasis of vascular lesions and soft tissue, including, the treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1-4.0 mm diameter) of the leg.

The Real Time Chiller is indicated for use in cooling the epidermis at the treatment site prior to, during and after light or laser treatment in general surgery, plastic surgery and dermatology to reduce pain during and/or associated with light or laser treatment (via partial anesthesia from cooling), to reduce discomfort during and/or associated with light or laser treatment, to minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light or laser treatment, thus reducing possible complications such as scabbing, scarring, hyper- and/or hypopigmentation, to allow the use of higher light or laser fluences for light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions), to reduce potential side effects of light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions), and to protect the skin from thermal necrosis, thus reducing possible complications such as scabbing, scarring, hyper- and/or hypopigmentation.

VI. Rationale for Substantial Equivalence

The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems share the same general indications for use, and therefore is substantially equivalent for use in surgical, aesthetic and cosmetic applications to the ESC Medical Systems EpiLight intense pulsed light systems (K991935, K994014), the ESC Medical Systems MultiLight intense pulsed light systems (K994014), the ESC Medical Systems Photoderm HR intense pulsed light systems (K991935), the ESC Medical Systems Photoderm Nd:YAG Accessory (K980537), the ESC Medical Systems Photoderm PL intense pulsed light systems (K960772), the ESC Medical Systems Photoderm VL intense pulsed light system (K950493), the Candela SPTL-1e Pulsed Dye laser system (K011092), the Candela Dynamic Cooling Devices (K001589 & K951033), the MedArt 520 Cooling System (K000503), the OptoMed DermaCool System and Handpieces (K990417), and the Coherent Epidermal Chiller Tip (K960032). In addition, clinical data demonstrated that

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the Lumenis Family of IPL/Nd:YAG laser systems (1064 nm) are safe and effective when indicated for use in specific applications in the medical specialties of general and plastic surgery, and dermatology.

VII. Safety and Effectiveness Information

Clinical data was provided to demonstrate that the Lumenis Family of IPL/Nd:YAG laser systems (1064 nm) are safe and effective, when indicated in specific applications in the medical specialties of general and plastic surgery, and dermatology. Performance data was provided to demonstrate that the Cooling Head integrated into the Treatment Head of the delivery handpiece for the Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems operates in accordance with its specifications.

VIII. Conclusion

The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems were found to be substantially equivalent to the predicate ESC Medical Systems EpiLight intense pulsed light systems (K991935, K994014), the ESC Medical Systems MultiLight intense pulsed light systems (K994014), the ESC Medical Systems Photoderm HR intense pulsed light systems (K991935), the ESC Medical Systems Photoderm Nd:YAG Accessory (K980537), the ESC Medical Systems Photoderm PL intense pulsed light systems (K960772), the ESC Medical Systems Photoderm VL intense pulsed light system (K950493), the Candela SPTL-1e Pulsed Dye laser system (K011092), the Candela Dynamic Cooling Devices (K001589 & K951033), the MedArt 520 Cooling System (K000503), the OptoMed DermaCool System and Handpieces (K990417), and the Coherent Epidermal Chiller Tip (K960032). The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems shares similar indications for use, design features, and similar functional features as, and thus are substantially equivalent to, the currently marketed predicate devices.

Clinical data was provided to demonstrate that the Lumenis Family of IPL/Nd:YAG laser systems (1064 nm) are safe and effective, when indicated in specific applications in the medical specialties of general and plastic surgery, and dermatology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

Ms. Anne C. Worden
Acting Vice President, Regulatory
and Quality Assurance
Lumenis, Inc.
2400 Condensa Street
Santa Clara, California 95051

Re: K020839
Trade/Device Name: Lumenis Family of Intense Pulsed-Light (IPL)
and IPL/Nd:YAG Laser Systems and the Real Time Chiller
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: July 11, 2002
Received: July 15, 2002

Dear Ms. Worden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2
Indications For Use Statement as Requested by FDA

510(k) Number (if Known): K020839

Device Name: Lumenis Family of Intense Pulsed-Light (IPL) Systems & Combination IPL Systems and Nd:YAG Laser Systems and the Real Time Chiller

Indications For Use:

The Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG laser systems (and the delivery accessories that are used with them to deliver light and/or laser energy) are indicated for use in surgical, aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology as follows:

➢ Intense Pulsed Light Energy/Wavelengths (515 - 1200 nm):

The 515 – 1200 nm intense pulsed light wavelengths are indicated for:

- The treatment of tattoos and benign pigmented epidermal and cutaneous lesions including warts, scars and striae;
- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations;
- The removal of unwanted hair from all skin types, and to effect stable long-term, or permanent[8], hair reduction in skin types I-V through selective targeting of melanin in hair follicles.

➢ Nd:YAG Laser Wavelength (1064 nm):

The 1064 nm wavelength produced by the Nd:YAG laser is indicated for:

- The coagulation and hemostasis of vascular lesions and soft tissue, including:
  - Treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1 – 4.0 mm diameter) of the leg.

[8] Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after a treatment regimen.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices
K020839
510(k) Number

Over-The-Counter Use

(Optional Format 1-2-96)

510(k) Number (if Known): K020839

Device Name: Lumenis Family of Intense Pulsed-Light (IPL) Systems & Combination IPL Systems and Nd:YAG Laser Systems and the Real Time Chiller

Indications For Use: *****Continued from Previous Page*****

➢ Real Time Chiller:

The Real Time Chiller is indicated for use in cooling the epidermis at the treatment site prior to, during and after light or laser treatment in general surgery, plastic surgery and dermatology to:

- Reduce pain during and/or associated with light or laser treatment (via partial anesthesia from cooling);
- Reduce discomfort during and/or associated with light or laser treatment;
- Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light or laser treatment, thus reducing possible complications such as scabbing, scarring, hyper- and/or hypopigmentation;
- Allow the use of higher light or laser fluences for light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions); and
- Reduce potential side effects of light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number K020839